UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,909	07/21/2003	Eileen Tozer	564462005300	7087

7590 02/14/2006

Gregory P. Einhorn
Morrison & Foerster LLP
Suite 500
3811 Valley Centre Drive
San Diego, CA 92130

EXAMINER	
BERTAGNA, ANGELA MARIE	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,909	TOZER ET AL.	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,14,15,29,33,35,40,42-45,48,49,51,54,56,58,60,78,79,84,86-88,90,92-94,98, 101, 105-107, 111, 113, 116, 138, 143, 149, 152, 164-165, 174-175, 177, 182, 184, and 187-192.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,14,15,29,33,35,40,42-45,48,49,51,54,56,58,60,78,79,84,86-88,90,92-94,98,101,105-107,111,113,116,138,143,149,152,164,165,174,175,177,182,184 and 187-192.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 14-15, 29, 33, 35, 40, 43-45, 48, 49, 58, 87, 188, 189 and 192, drawn to a isolated or recombinant nucleic acid, a nucleic acid probe, an amplification primer pair, an expression cassette, a vector, a cloning vehicle, a transformed cell comprising a vector, an antisense oligonucleotide, and an array of immobilized nucleic acids, classified in class 536, subclass 23.1.

II. Claims 42, 111 and 113, drawn to a method of amplification, classified in class 435, subclass 91.2.

III. Claim 51, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

IV. Claims 54 and 56, drawn to a transgenic plant and seed, classified in class 800, subclass 295.

V. Claims 60, 78-79, 84, 86 and 190-191, drawn to an isolated or recombinant polypeptide, classified in class 530, subclass 350.

VI. Claims 88 and 90, drawn to an antibody and hybridoma, classified in class 530, subclass 387.1.

VII. Claim 92, drawn to a method of isolating or identifying a fluorescent polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 93, drawn to a method of making an anti-fluorescent protein antibody, classified in class 800, subclass 6.

IX. Claim 94, drawn to a method of producing a recombinant polypeptide, classified in class 435, subclass 69.1.

X. Claim 98, drawn to a method of identifying an agent that changes the emission of a fluorescent polypeptide, classified in class 435, subclass 7.1.

XI. Claims 101 and 105, drawn to a computer system and computer readable medium, classified in class 700, subclass 1.

XII. Claims 106-107, drawn to a method of identifying a sequence feature, classified in class 700, subclass 91.

XIII. Claims 116, 138, and 143, drawn to methods of creating variant nucleic acids, classified in class 435, subclass 440.

XIV. Claim 149, drawn to a method for determining the functional fragment of a polypeptide, classified in class 435, subclass 5.

XV. Claim 152, drawn to a method of producing a chimeric polypeptide, classified in class 435, subclass 69.7.

XVI. Claim 164, drawn to a method for producing a fluorescently tagged nucleic acid, classified in class 536, subclass 25.3.

XVII. Claim 165, drawn to a method for using a polypeptide as a fluorescent marker, classified in class 435, subclass 5.

XVIII. Claims 174 and 175, drawn to methods of gene therapy, classified in class 514, subclass 44.

XIX. Claims 177, 182, 184 and 187, drawn to methods of assessing the effect of environmental conditions or test agents on gene expression, classified in class 435, subclass 6.

2. Further Restriction Requirement Applicable to All Groups:

Additionally, each of Groups I-XIX named above is subject to a further restriction. Applicant is required to further elect a single, specific nucleic acid sequence and a single, specific amino acid sequence for examination.

With regard to the election of specific sequences, different sequences comprise nucleic acid (or amino acid) sequences that are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claims shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

The search and examination of all possible groups would pose an enormous burden on the examiner and on the PTO search resources. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter due to all of the inventions' different gene sequences would require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore the restriction is deemed proper.

3. Inventions I, III-VI and XI are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation, different functions and different effects. The nucleic acid products of Group I can function in a variety of molecular biology methods, such as amplification, hybridization and cloning, whereas the transgenic animal of Group III can function as a model system for a particular disease. The transgenic plant and seed of Group IV are unrelated to the products of Groups I and III, because they can function in methods of crop improvement. The polypeptides of Group V are unrelated to Groups I, III and IV, because they can function in specific protein binding assays. The antibody and hybridoma of Group VI are unrelated to the products of Groups I, III, IV and V, because unlike these other products, they can function in immunoassays. The computer system and computer readable medium of Group XI are unrelated to Groups I, III, IV, V and VI,

because it can function in a variety of data manipulation and storage processes unrelated to the biochemical methods in which the other products may be used.

4. Inventions II, VII-X, and XII-XIX are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions, modes of operation and effects. The methods of Groups II, VII-X and XII-XIX are drawn to very different processes: amplifying a nucleic acid, isolating a fluorescent protein, making an antibody, producing a recombinant protein, screening for a agent that modifies fluorescence emission, sequence analysis, creating variant nucleic acids, determining the functional portion of a protein, producing a chimeric protein, producing a fluorescently tagged nucleic acid, using a protein as a fluorescent marker, gene therapy and altering gene expression. These methods do not share common method steps, and practice of the methods does not lead to a common result. Therefore, these methods are unrelated.

5. Invention I is related to Inventions II, VIII, IX, XII, XIII, XVI, XVIII and XIX as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the differently sized nucleic acids of Group I may be used as mass

standards in agarose gel electrophoresis – a materially different process than the claimed processes.

6. Invention I is unrelated to Inventions VII, X, XIV, XV, and XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid products of Group I are not disclosed as capable of use in the protein-based methods of Groups VII, X, XIV, XV and XVII. Furthermore, as discussed above, the nucleic acid products of Group I may function in a variety of processes, such as cloning, amplification, hybridization and sequencing, that are unrelated to the methods of Groups VII, X, XIV, XV and XVII.

7. Invention III is related to Inventions VIII and XIX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transgenic animal of Group III could be used to breed additional transgenic animals – a materially different process than producing an antibody or determining the effect of a test agent on gene expression.

8. Invention III is unrelated to Inventions II, VII, IX, X, and XII-XVIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic animal of Group III is not

disclosed as capable of use in the methods of Groups II, VII, IX, X and XII-XVIII. These methods require the nucleic acid products of Group I and/or the protein products of Group V, but do not require the transgenic animal of Group III. Furthermore, the transgenic animal of Group III may be used in breeding methods unrelated to the methods of Groups II, VII, IX, X and XII-XVIII.

9. Invention IV is unrelated to Inventions II, VII-X, and XII-XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the transgenic plant or seed of Group IV is not disclosed as capable of use in the methods of Groups II, VII-X and XII-XIX, which require the nucleic acid products of Group I and/or the protein products of Group VI and/or the transgenic animal of Group III.

10. Invention V is related to Inventions VIII, X, XII, XIV-XIX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the differently sized fluorescent polypeptides of Group V may be used as size standards in polyacrylamide gel electrophroesis or mass spectrometry.

11. Invention V is related to Inventions VII and IX as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product

or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptides of Group V can be made by chemical synthesis.

12. Invention V is unrelated to Inventions II and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Groups II and XIII do not require the proteins of Group V, but rather the nucleic acids of Group I.

13. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Group VI can be used as a molecular weight marker in polyacrylamide gel electrophoresis.

14. Inventions VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the antibody may be produced using a tissue cell culture line rather than an animal.

15. Invention VI is unrelated to Inventions II, IX, X, and XII-XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use with the antibody of Group VI. Instead, these methods require the nucleic acids of Group I, the proteins of Group VI and/or the transgenic animal of Group III.

16. Inventions XII and XI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the comparison of protein and/or nucleic acid sequences may be performed by hand.

17. Invention XI is unrelated to Inventions II, VII-X, and XII-XIX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II, VII-X and XII-XIX do not require the use of a computer system or computer readable medium.

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

19. Because these inventions are distinct for the reasons given above and the search required for Groups I-XIX is not coextensive, restriction for examination purposes as indicated is proper. A search for the products of Groups I, III-VI and XI would be directed to the specific products and would not require search terms directed to methods of making and/or using the products. Since the products are unrelated, as discussed above, a search of the products also cannot be performed coextensively. A search for the methods of Groups II, VII-X and XII-XIX is also not coextensive, because as discussed above, these methods are unrelated, comprising different method steps and results.

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

Angela Bertagna
Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER
2/10/06

amb